510(k) Summary

K101148

1. COMPANY INFORMATION

Cincinnati Sub-Zero, Inc.
12011 Mosteller Road
Cincinnati, Ohio 45241-1528
Telephone: (513) 772-8810
FAX: (513) 772-9119

OCT 19 2010

2. CONTACT INFORMATION

Steven J. Berke
President and CEO
Telephone: (513) 772-8810 ext 3212
FAX: (513) 772-9119
Email: sjberke@cszinc.com

3. DATE PREPARED: April 22, 2010

4. DEVICE TRADE NAME: WarmAir® Model 135 Hyperthermia System including blankets

5. COMMON NAME: Temperature management system

6. CLASSIFICATION NAME: System, Thermal Regulating

7. CLASSIFICATION REGULATION: 21 CFR 870.5900

8. CLASSIFICATION PRODUCT CODE: DWJ

9. PANEL: Cardiovascular

10. DEVICE CLASSIFICATION: Class II

11. IDENTIFICATION OF PREDICATES:
    a. K942599 and K942790 Cincinnati Sub-Zero WarmAir Hyperthermia system Model 133 and blankets
    b. K011907 SIMS Level 1 Snuggle Warm 4000/Equator 5000 Convective Warming System and blanket (now sold by Smiths Medical ASD)
    c. K040632 Smiths Medical ASD Sterile Cardiac Blanket component of Snuggle Warm 4000 Convective Warming System
    d. K960167 Bair Hugger Model 505 Total Temperature Management System

DEVICE DESCRIPTION

The WarmAir 135 Hyperthermia System is a patient temperature management device which provides forced air warmed by the controller to a blanket that is placed over or under adult, pediatric or neonatal patients in order to warm them. The heated air is blown through connecting flexible hose to a disposable blanket to provide patient therapy by the means of warmed air.

The system can be used in long-term care facilities, surgical facilities, hospitals including the Post-anesthesia Care Unit (PACU), Intensive Care Unit (ICU), Surgical Intensive Care Unit (SICU), Emergency Room (ER), Operating Room (OR), recovery room, medical and surgical floors, emergency department, or any other department or hospital facility requiring patient temperature management.

DESCRIPTION OF THE DEVICE CHANGES

The predicate WarmAir System, Model 133 used a thermistor for the primary temperature safety and a bulb capillary type or thermostat for the secondary temperature safety. The new Model 135 uses a thermistor for the primary temperature safety and a snap disc thermostat for the secondary temperature safety. The specifications for the primary and secondary safety shut-down set points have changed from the prior model.

INTENDED USE

The WarmAir 135 patient warming system is intended to prevent hypothermia and/or reduce cold discomfort before, during, and after surgical procedures. The thermal regulating system is used to raise a patient's temperature and/or maintain a desired patient temperature through convective heat transfer from the controller to a warm-air-heated blanket. The single-patient use blankets transfer the thermal energy to adult, pediatric, or neonate patients to obtain/maintain normal body temperature. It is intended for use by appropriately trained healthcare professionals in clinical environments.

BENCH TESTS PERFORMED IN DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Bench testing was performed in order to validate the design according to the company's specified design requirements, and to demonstrate the new systems are substantially equivalent to the predicate devices.

The following bench tests were performed:

- Temperature Performance Testing
- System Safety Limit Testing
- Transportation Testing
- Blanket Structural Integrity Testing

In addition, the new systems meet the applicable requirements of the following standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995.

- IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

All necessary testing has been performed for the WarmAir 135 Hyperthermia system to assure substantial equivalence to the predicate devices.

SUBSTANTIAL EQUIVALENCE

The modified devices have the same intended use as the predicates and similar technological characteristics that do not raise new types of questions of safety and effectiveness and are therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Cincinnati Sub-Zero
c/o Mr. Steven J. Berke
President and CEO
12011 Mosteller Road
Cincinnati, OH 45241-1528

OCT 19 2010

Re: K101148
WarmAir 135 Hyperthermia System and Blankets
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: September 28, 2010
Received: September 30, 2010

Dear Mr. Berke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

OCT 19 2010

510(k) Number (if known): K101148

Device Name: Warm Air® Model 135 and Blankets

Indications for Use:

The WarmAir® 135 patient warming system is intended to prevent hypothermia and/or reduce cold discomfort before, during, and after surgical procedures. The thermal regulating system is used to raise a patient's temperature and/or maintain a desired patient temperature through convective heat transfer from the controller to a warm-air-heated blanket. The single-patient use blankets transfer the thermal energy to adult, pediatric or neonate patients to obtain/maintain normal body temperature. It is intended for use by appropriately trained healthcare professionals in clinical environments.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Posted November 13, 2003)

(Division Sign-Off)
Division of Cardiovascular Devices
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